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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/344,132	12/19/99	SAWAN	SUR-008

021320 HM12/1219  
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EXAMINER  
SHARAREH, S

ART UNIT	PAPER NUMBER
1619	7

DATE MAILED: 12/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

# Office Action Summary

Application No.  
09/392,842

Applicant(s)

Sawan et al

Examiner  
Shahnam Sharareh

Group Art Unit  
1619



☒ Responsive to communication(s) filed on Sep 9, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11, 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-88 is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-88 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1619

## DETAILED ACTION

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-57, drawn to antimicrobial compositions and methods of use thereof, classified in 424, subclass 400.
  - II. Claims 58-71, drawn to methods of enhancing the duration of efficacy of a dermal formulation, classified in class 522, subclass 1+ or class 524, subclass 1+.
  - III. Claim 72-86, drawn to methods of imparting moisture and sweat resistance, classified in class 514, subclass 635+.
  - IV. Claim 87-88, drawn to methods of detecting the presence of a marker, classified in class 424, subclass 9.6.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II or III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the composition can simply be used for its antimicrobial effects. Methods of enhancing the duration of dermal efficacy, or detecting the presence of a marker requires

Art Unit: 1619

materially different process and components than simple application of the instant composition.

Therefore, the process of use can be practiced by materially different elements and compositions.

3. Inventions II, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are various patentably distinct methods that utilize different components, apparatuses, compositions and possess distinct outcomes.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. Claims 1-88 generic to a plurality of disclosed patentably distinct species comprising different biguanide polymeric moieties (claims 1-3, 39, 59-61, 74-75, 80), and various substantially water-insoluble organic compound having patentably distinct chemical functional groups (claims 6-7, 22, 26, 41-42, 44, 66-69, 71, 81-83, 86). It is noted that the claims encompass such final products as those set forth in Examples 1-14 and listed on pages 22-35 of the specification. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that

Art Unit: 1619

all claims are generic is considered non-responsive unless accompanied by an election. By species is meant a single compound. The compound may be named in any of four ways (or any combination thereof): (a) according to the IUPAC standard, (b) by a pictorial representation of the compound, (c) by setting forth the specific chemical group that each variable of the Markush group represents, or (d) by naming a claim or an example which itself sets forth a single compound.

Since the instant claims are drawn to a antimicrobial compositions of matter which contains more than one group of monomeric entities, a single unit (as described above) should be elected for each group of compositions. It is not necessary to elect a single compound for groups of compounds which are inert and have no bearing on the patentability of the composition (e.g. it would not usually be necessary to elect which solvent or buffer system the composition will be associated with.) For the instant election of species, the type of biguanide polymer should be specified.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.


Art Unit: 1619

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

ss 12/13/2000

  
DIANA DUDASH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600